

Voting Questions

LUTONIX® 035 Drug Coated Balloon PTA Catheter

The LUTONIX DCB is a combination device/drug product incorporating an over-the-wire percutaneous transluminal angioplasty (PTA) catheter with paclitaxel drug coating on the surface of the balloon

The sponsor has proposed the following Indications for Use:

“The LUTONIX® 035 Drug Coated Balloon PTA Catheter is indicated for improving luminal diameter for the treatment of obstructive de novo or non-stented restenotic lesions (≤ 15 cm in length) in native femoropopliteal arteries having reference vessel diameters of 4 mm to 6 mm.”

The following questions relate to the approvability of the LUTONIX® 035 Drug Coated Balloon PTA Catheter. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented at the panel meeting.

Voting Question 1:

Is there reasonable assurance that the LUTONIX® 035 Drug Coated Balloon PTA Catheter is safe for use in patients who meet the criteria specified in the proposed indication?

Voting Question 2:

Is there reasonable assurance that the LUTONIX® 035 Drug Coated Balloon PTA Catheter is effective for use in patients who meet the criteria specified in the proposed indication?

Voting Question 3:

Do the benefits of the LUTONIX® 035 Drug Coated Balloon PTA Catheter for use in patients who meet the criteria specified in the proposed indication outweigh the risks for use in patients who meet the criteria specified in the proposed indication?